

DETAILED ACTION

Summary

Receipt of Applicant's Response and Amended Claims filed on 2/06/08 is acknowledged. Claims 1-8 and 21-24 are pending. Claims 1-8 and 21-24 are rejected.

Due to Applicant's amendments the 35 U.S.C. 102(b) and 103 rejections of record by US 5,858,398 ('398) as evidenced by US 3,578,591 ('591) is hereby **withdrawn**.

NEW REJECTIONS

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,482,927 ('927).

The limitations of claims 1-8 and 21-24 are taught:

- '927 teaches a biologically active protein is dissolved in water or a suitable solvent, alone or in combination with stabilizing agents and that the solution is either lyophilized or spray dried to obtain a free flowing powder (abstract).

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- '927 teaches that rbST and BSA are preferred, but that any protein or peptide having therapeutic or biological activity can be used (col. 2, lines 50-66).
- Surfactant/stabilizers such as deoxycholic acid and polysorbate 80 are taught by '927.
- Example 5 teaches the making of a stabilized preparation of rbSt and stabilizer alone using deoxycholic acid, polysorbate 80, etc.
- '927 teaches that the complex may be administered in a carrier in vivo such as vegetable and/or mineral oil, and/or any fats and waxes of natural or synthetic origin, which are deemed suitable as biocompatible materials (col. 4, lines 16-23).

Claims 1-8 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,888,416 ('416).

The limitations of claims 1-8 and 21-24 are taught:

- '416 teaches a method of preparing a dried protein product comprising an aqueous solution comprising a mixture of protein and an ionic detergent and drying said protein-detergent mixture (abstract, claim 1).
- '416 teaches that the detergent is an ionic detergent (cationic or anionic) such as an alkyl sulfate, specifically sodium dodecyl sulfate (claims 4-7). '416 teaches that the selection of a cationic or anionic detergent depends on whether the protein of interest is characterized by positive or negative charges and that the anionic detergent will have an alkyl group of up to about 16 carbon atoms (col. 4,

lines 1-10, Examples). The instant specification teaches that functional groups such as "steric stabilizers" include alkyl chains (p. 17, lines 10-13), and as such a detergent with an alkyl chain as taught by '416 meets the limitation of claim 3.

- '416 teaches polypeptides and proteins, both natural and synthetic proteins and polypeptides including those produced using recombinant DNA techniques and biologically active derivatives, specifically bovine or porcine somatotropin (col. 2, lines 46-64).
- '416 teaches that prior to administration to a living being via intravenous injection or infusion pump the dried product is added to a solution and Examples teach adding to PBS (col. 4, lines 15-20 and Examples). '416 teaches in vitro experiments desired to simulate in vivo use of the protein products show that the detergent does not adversely affect the bioactivity of the protein (col. 4, lines 15-24). Example 2 teaches administration to rats.

Claims 1-8 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/08599 ('599).

The limitations of claims 1-8 and 21-24 are taught:

- '599 teaches a hydrophobic ion-pairing (HIP) complex formed by an anionic surfactant such as sodium dodecyl sulfate (SDS) to a polypeptide, protein or other molecule in solution and that the isolated HIP precipitate can be redissolved in an organic solvent to form a homogeneous solution (abstract, claim 1).

- '599 teaches that SDS is not the only surfactant but that any hydrophobic material that is the salt of an acid can be employed including sulfates, sulfonates, phosphates, carboxylates, etc and alkyl chains of 8-18 carbons (pg. 2, lines 14-20; pg. 17, line 21-pg. 18, line 10) and that CTAB is a cationic detergent that can be used for a negatively charges peptide.
- '599 teaches various proteins such as interleukins, growth factors, etc (pg. 9, lines 9-16).
- '599 teaches that the precipitate is dissolved in an organic solvent such as octanol, ethanol, propylene glycol, etc (pg. 7, line 35-pg. 8, line 4; pg. 10, lines 26-32; pg. 15, lines 17-25).
- Example 17 teaches the administration of a HIP complex dissolved in an organic solution for administration of a protein to a patient.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,482,927 ('927).

The limitations of claims 1-8 and 21-24 are taught:

- '927 teaches a biologically active protein is dissolved in water or a suitable solvent, alone or in combination with stabilizing agents and that the solution is either lyophilized or spray dried to obtain a free flowing powder (abstract).
- '927 teaches that rbST and BSA are preferred, but that any protein or peptide having therapeutic or biological activity can be used (col. 2, lines 50-66).
- Surfactant/stabilizers such as deoxycholic acid and polysorbate 80 are taught by '927.
- Example 5 teaches the making of a stabilized preparation of rbSt and stabilizer alone using deoxycholic acid, polysorbate 80, etc.
- '927 teaches that the complex may be administered in a carrier in vivo such as vegetable and/or mineral oil, and/or any fats and waxes of natural or synthetic origin, which are deemed suitable as biocompatible materials (col. 4, lines 16-23).

Response to Arguments

Applicant's arguments with respect to claims 1-8 and 21-24 have been considered but are moot in view of the new grounds of rejection necessitated by applicants' amendments.

Conclusions

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany P. Barham whose telephone number is 571-272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bethany Barham
Examiner-1615

/Michael P Woodward/
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